IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JOHN C. HALL	)	
Individually,	)	
	)	
PLAINTIFFS,	)	
	)	
v.	)	**CASE NO. _____**
	)	
AbbVie, Inc, West-Ward Pharmaceuticals	)	
And Eli Lilly and Company	)	
	)	
DEFENDANTS.	)	

COMPLAINT

COMES NOW, Plaintiff, John C. Hall, by and through the undersigned counsel, and file this Complaint and causes of action against AbbVie Inc., West-Ward Pharmaceuticals and Eli Lilly and Company (hereinafter "Defendants") and states as follows:

INTRODUCTION

1. This case involves the prescription drug Androgel, which is manufactured, sold, distributed and promoted by Defendants as a testosterone replacement therapy. This action arises out of the Defendants' unlawful, unfair, and deceptive practices related to the manufacturing, sale, labeling, pre- and post-marketing testing, and marketing of this product.

2. This case involves the prescription drug Axiron, which is manufactured, sold, distributed and promoted by Defendant Eli Lilly and Company as a testosterone replacement therapy. This action arises out of the Defendants' unlawful, unfair, and deceptive practices related to the manufacturing, sale, labeling, pre- and post-marketing testing, and marketing of this product.

3. This case involves the prescription drug Testosterone Cypionate, which is manufactured, sold, distributed and promoted by Defendant West-Ward Pharmaceuticals as a testosterone

replacement therapy. This action arises out of the Defendants' unlawful, unfair, and deceptive practices related to the manufacturing, sale, labeling, pre- and post-marketing testing, and marketing of this product.

4. Defendants , respective to their individual drugs, misrepresented that Androgel, Axiron and Testosterone Cypionate are a safe and effective treatment for hypogonadism or "low testosterone," when in fact the drug causes serious medical problems, including life threatening adverse events including but not limited to the development, promotion, and/or increased risk of serious adverse cardiac conditions.

5. Androgel, Axiron and Testosterone Cypionate are an exogenous form of the androgen testosterone. It regulates the expression of platelet TXA2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

6. AndroGel and Axiron are delivered transdermally and is applied to the skin in the form of a gel. AndroGel is available in either a 1% or 1.62% concentration.

7. Testosterone Cypionate is administered by injection.

8. Defendants failed to adequately warn physicians about the risks associated with the AndroGel and the monitoring required to ensure their patients' safety.

9. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing

deterioration in the ability to play sports," and "falling asleep after dinner." Available at: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

10. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "LowT". Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

11. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially as have the sales of testosterone replacement therapy.

12. Defendants failed to adequately warn physicians about the risks associated with the Androgel, Axiron and Testosterone Cypionate and the monitoring required to ensure their patients' safety.

13. As a result of using Androgel, Axiron and Testosterone Cypionate, John C. Hall, suffered a myocardial infarction resulting in physical and emotional pain and suffering.

PARTIES

14. Plaintiff John C. Hall is a resident of and domiciled in Baltimore County, Maryland.

15. AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

16. Eli Lilly and Company is a corporation organized and existing under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Marion County, Indiana 46285.

17. West-Ward Pharmaceuticals is a corporation organized and existing under the laws of New Jersey with its principal place of business at 401 Industrial Way West, Eatontown, Monmounth County, New Jersey 07724.

Jurisdiction and Venue

18. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

19. Venue is proper in this judicial district pursuant to 28 U.S. Code § 1407 under which the Joint Panel on Multidistrict Litigation transferred venue of all testosterone replacement litigation to the Northern District of Illinois, MDL No. 2545, In re: Testosterone Replacement Therapy Products Liability Litigation.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, inter alia, a substantial part of the events or omissions giving rise to the Plaintiff's claims occurred in, and/or because the one or more of the Defendants reside in, and/or transact business in, this district.

GENERAL ALLEGATIONS

21. This action is for damages brought on behalf of the Plaintiff John C. Hall who was prescribed and supplied with, received and who has taken and applied the prescription drugs Androgel, Axiron and Testosterone Cypionate, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed,

sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff John C. Hall to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

22. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

23. At all times herein mentioned, Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drugs Androgel, Axiron and Testosterone Cypionate for the use and application by the Plaintiff.

24. At all times herein mentioned, Defendants were authorized to do business within the State of Maryland and the whole of the United States.

25. At all times herein mentioned, Defendant's officers and directors participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

26. Plaintiff files this lawsuit within the applicable limitations period. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the

conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drugs Androgel, Axiron and Testosterone Cypionate are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

FACTUAL ALLEGATIONS

Hypogonadism and the Development of Testosterone Therapy

27. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

28. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

29. In men, testosterone levels normally begin a gradual decline after the age of thirty.

30. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone. Hypogonadism can be the result of a medical condition, a result of taking certain medication, a consequence of injury, or can occur through the natural aging process. Hypogonadism can also begin during fetal development, before puberty, or during adulthood.

31. There are two basic types of hypogonadism, primary and secondary. Primary hypogonadism is the result of a problem in the testicles while secondary hypogonadism is the result of an issue in the hypothalamus or pituitary glands. Either type may be the result of an inherited trait or something that occurs later in life, such as injury or an infection. The drug at

issue is developed for and approved by the FDA for treatment of primary hypogonadism and hypogonadotropic hypogonadism (a form of secondary hypogonadism).

32. The slow, but steady, decrease of testosterone levels is a normal part of the aging process. In fact, studies indicate that a reduction of approximately 1% a year after the age of 30 is normal. This decrease in and of itself is not hypogonadism and is not intended to be treated with testosterone replacement therapy.

Defendants Testosterone Replacement Therapy Drugs

33. Defendants are engaged in the business of manufacturing, designing, distributing, marketing, and/or selling prescription drugs, including Androgel, Axiron and Testosterone Cypionate.

34. Upon information and belief, The Food and Drug Administration ("FDA") approved Androgel for the treatment of various forms of hypogonadism in adult males in February 28, 2000.

35. Upon information and belief, The Food and Drug Administration ("FDA") approved Axiron for the treatment of various forms of hypogonadism in adult males on or around November 23, 2010.

36. Upon information and belief, The Food and Drug Administration ("FDA") approved Testosterone Cypionate for the treatment of various forms of hypogonadism in adult males in 1979 and approved West-Ward Pharmaceuticals version on or around December 17, 2012.

37. Since the FDA approved the drugs at issue, Defendants have sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels and necessitate

treatment with testosterone replacement, by and through, among other methods, the use of sales representatives.

38. Defendants and their officers, agents, sales representatives, and employees purposefully downplayed, understated, and outright ignored the health hazards and risks associated with using testosterone therapy.

39. Defendants and their officers, agents, sales representatives, and employees concealed material, relevant information from consumers and minimized user and prescriber concern regarding the safety of testosterone therapy.

40. Defendants and their officers, agents, sales representatives, and employees falsely represented that the Defendants adequately tested the drugs at issue for all likely side effects.

41. Androgel, Axiron and Testosterone Cypionate may produce undesirable side effects to patients who use the drugs, including but not limited to: blood clots, pulmonary embolism, myocardial infarction, stroke, and death.

42. In some patient populations, Androgel, Axiron or Testosterone Cypionate use may increase the incidence of myocardial infarctions and death by over 500%.

43. Defendants' aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

44. As a result, many men are taking testosterone therapy without understanding the true risks associated therewith.

Testosterone Replacement Therapy and Increased Risk of Serious adverse cardiac conditions.

45. Defendants failed to adequately test and study Androgel, Axiron and Testosterone Cypionate both pre- and post-marketing of this drug to consumers, evidenced by the increasing medical literature and studies showing the adverse events associated with the use of testosterone therapies such as Androgel, Axiron and Testosterone Cypionate.

46. Defendants purposefully downplayed, understated, and/or outright ignored the health hazards and risks associated with using testosterone therapy.

47. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendant Abbvie and Abbott's predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men." The Defendant represented to the FDA that it would market and sell the drug to this patient population of one million men who have an actual diagnosis of hypogonadism with an associated medical condition. This was a false representation that it made to the FDA in order to obtain approval of the drug.

48. In 2000, when the FDA approved AndroGel, the company announced that the market had increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 - 2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription. A Canadian study showed that only about 6.3% of men who were prescribed testosterone actually met the diagnostic criteria for hypogonadism.

49. At all times material hereto, and since the time that AndroGel first received approval from the FDA, the Defendants knew and understood the FDA-approved indications for clinical use of the AndroGel product.

50. Defendants expanded the indications for use by promoting and detailing “Low T” as an acquired form of hypogonadism, and advantaged intentional ambiguity in the AndroGel product labeling as a basis for “label expansion” and “off-label” marketing, detailing, and promotion to physicians.

51. In 2000, when reviewing the drug's advertisements, the FDA told AndroGel's maker that "claims and representation that suggest that AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." The drug, the FDA said, was only approved for men with hypogonadism. Despite this admonition from the FDA, the Defendants continued to market and promote testosterone replacement therapy for “andropause” and “LowT”.

52. Defendants coordinated a massive advertising campaign targeted toward men who did not have Hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. The direct to consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called “LowT”, which was a term for low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

53. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone

replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

54. Defendants’ national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", “Are you sad and/or grumpy?”, and “Do you have a lack of energy?”

55. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, “Don’t make it too long and make it somewhat sexy.” Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has “no trouble calling it a crappy questionnaire” and that it is “not ideal.” This is the “Low T Quiz” used on the “IsItLowT” website. Natasha Singer, Selling that New-Man Feeling, Nov. 23, 2013, N.Y. TIMES.

56. Since the FDA approved AndroGel for a very specific medical condition called Hypogonadism, Defendants have also sought to convince primary care physicians that Hypogonadism is synonymous with “LowT” and that low testosterone levels are widely under-

diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

57. While running its disease awareness campaign, Defendants promote their products as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

58. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

59. The Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "LowT", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendant marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

60. A 2004 memo on AndroGel sales strategies said the sales force was putting extra emphasis on rural areas, since "rural doctors are typically very accessible, give us plenty of time to teach them the right way to diagnose and treat, and they have the patients."

61. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular

checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

62. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

63. Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.

64. We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

65. Defendants' advertising paid off in a return of $1.4 billion in sales during the past year (2013), making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, Are Testosterone Drugs the Next Viagra?, May 10, 2012, Bloomberg Businessweek, available at: http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

66. In 2009 a whistle-blower lawsuit filed by relator John King and Jane Doe on behalf of the United States and 23 individual states alleged that AndroGel was marketed and promoted for off-label uses, including osteoporosis, sexual dysfunction, depressions and obesity.

67. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. See Singer, Selling That New-Man Feeling, supra; See also, Larry Dobrow, All-star large pharma marketing team of the year: Androgel. Jan. 2, 2013, Medical Marketing & Media, available at: http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

68. The Defendants engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "LowT".

69. The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of AndroGel is safe for human use as a treatment for "LowT", even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

70. At all times material hereto, Defendant's marketing strategy included the use of sales or drug detailing representatives ["reps"] and marketing and brand team personnel who performed on-line and in-person AndroGel product detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and

conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

71. The Defendant's drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the AndroGel product, as well as discount and/or rebate coupons to give to patients for the purchase of AndroGel.

72. Defendant's drug "reps" detailed and marketed AndroGel to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

73. Defendant denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

74. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

75. The Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

76. Defendants marketed, promoted, and detailed AndroGel for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the AndroGel product.

77. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

78. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

79. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

80. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

81. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

82. At all times material hereto, Defendant's marketing strategy included the use of sales or drug detailing representatives ["reps"] and marketing and brand team personnel who performed on-line and in-person Androgel, Axiron and Testosterone Cypionate product detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

83. The Defendant's drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the Androgel, Axiron and Testosterone Cypionate products.

84. Defendant's drug "reps" detailed and marketed Androgel, Axiron and Testosterone Cypionate to physicians as products approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

85. Defendants denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

86. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

87. The Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

88. Defendants marketed, promoted, and detailed Androgel, Axiron and Testosterone Cypionate for "off-label" use for the purpose of "label expansion," and detailed and promoted the products to physicians, and advertised the products to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the Androgel, Axiron or Testosterone Cypionate products.

89. A manufacturer may not introduce a drug into interstate commerce with intent that it be used for an "off-label" purpose.

90. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

91. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

92. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

93. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

94. The FDA did not, and never has, approved Androgel, Axiron or Testosterone Cypionate for the treatment of:

- age-related declines in testosterone levels in men;
- age-related symptoms;
- mood disorders, including depression or "grumpiness" or inability to concentrate;
- lack of sexual interest or decreased libido;
- disorders of erectile function or erectile dysfunction;
- loss of muscle mass; or,
- bone strength or density abnormalities.

Adverse Events and Serious Health Risks Caused by TRT.

95. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

96. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

97. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit1 and serum estradiol levels[2]. It can also cause increased platelet aggregation and vasoconstriction.

98. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

99. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

100. The clinical trial data submitted to the FDA for the approval of AndroGel showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

101. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

102. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

103. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

104. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

105. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

106. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

107. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

108. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

109. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in

[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.
[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.
[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

110. In a case control study of men in the Framingham cohort supra, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

111. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol.[16] Impaired contractile function results in numerous cardiovascular injuries and disease.

112. A study published in 2007 compared blood levels of testosterone and estradiol in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of estradiol in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, estradiol

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.
[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.
[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.
[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

levels in these heart attack patients were 180% higher, while bioavailable testosterone levels were nearly three times less than those of control patients.[18]

113. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[19]

114. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

115. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

116. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone.

[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.
[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006**Vol.** 290**no.** H2043-H2050**DOI:** 10.1152/ajpheart.01121.2005
[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

117. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

118. In a study published in 2013[21,] based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

119. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

120. Defendants and their officers, agents, sales representatives, and employees knew or should have known of the relationship between testosterone replacement therapies, including Androgel, Axiron and Testosterone Cypionate, and serious adverse cardiac conditions, along with numerous other adverse events, but failed to adequately warn consumers, including John C. Hall, of the known risk and association between Androgel, Axiron and Testosterone Cypionate and serious adverse cardiac conditions and increased risk of death.

SPECIFIC FACTUAL ALLEGATIONS

121. In or around March of 2011, John C. Hall was prescribed and began using Testosterone Cypionate, then prescribed and used AndroGel, and then prescribed and used Axiron and in each instance his use of these testosterone replacement drugs was consistent with the manufacturers instructions.

122. On or around September 15, 2011, John C. Hall, felt pressure in his chest and dialed an emergency 911 operator.

123. On September 15, 2011, Mr. Hall fell unconscious and remained in such a state for a significant period of time, approximately 18 days. After his arrival at the hospital, Mr. Hall was diagnosed with acute myocardial infarction with total occlusion of the left main artery. This particular type of acute myocardial infarction is referred to as the "widow-maker" for its ability to cause sudden death.

124. John C. Hall's use of Androgel, Axiron and Testosterone Cypionate caused him to suffer serious personal and emotional injuries, including but not limited to serious adverse cardiac conditions and the associated physical and mental pain and suffering and medical expenses that accompanied this injury.

CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

125. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

126. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

127. The Androgel, Axiron and Testosterone Cypionate manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the products created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

128. Defendants respectively failed to adequately warn consumers and/or their health care providers that Androgel, Axiron and Testosterone Cypionate could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

129. Defendants respectively failed to adequately warn consumers and/or their health care providers that while a patient was taking Androgel, Axiron and Testosterone Cypionate it was necessary to frequently monitor hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

130. The Androgel, Axiron and Testosterone Cypionate manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Androgel, Axiron and Testosterone Cypionate, Defendants failed to provide an adequate warning

to consumers and/or their health care providers of the product, knowing the products could cause serious injury.

131. As a direct and proximate result of John C. Hall's reasonably anticipated use of Androgel, Axiron and Testosterone Cypionate as respectively manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff, John C. Hall suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

Count Two – Negligence

132. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

133. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Androgel, Axiron and Testosterone Cypionate.

134. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Androgel, Axiron and Testosterone Cypionate to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and it sequelae, pulmonary embolism, and sudden cardiovascular death.

135. Defendants had a duty of care when it undertook to provide comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; and,

to educate and inform consumers and patients about "Low T;" and, to provide consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

136. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of Androgel, Axiron and Testosterone Cypionate to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

137. Defendant's duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

-hypogonadism and its diagnostic criteria;

-the FDA-approved indications for the clinical use of the Androgel, Axiron and Testosterone Cypionate products;

-the clinical safety and effectiveness profiles of Androgel, Axiron and Testosterone Cypionate; and,

-appropriate, complete, and accurate warnings concerning the adverse effects of Androgel, Axiron and Testosterone Cypionate, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

138. At all times herein mentioned, Defendants breaches its duty of care by negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Androgel, Axiron and Testosterone Cypionate and failed to adequately test and warn of the risks and dangers of Androgel, Axiron and Testosterone Cypionate as described herein.

139. The Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion, and as a result millions of men, including the Plaintiff, were prescribed Androgel,

Axiron or Testosterone Cypionate unnecessarily, and therefore needlessly exposed to serious health risks for which there were no or inadequate warnings.

140. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for Androgel, Axiron and Testosterone Cypionate, including Plaintiff's prescribing physician. Specifically, the FDA had not approved Androgel, Axiron or Testosterone Cypionate or any other testosterone-containing preparation for the treatment of "Low T."

141. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted the testosterone-containing products Androgel, Axiron and Testosterone Cypionate with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

142. Despite the fact that Defendants knew or should have known that Androgel, Axiron and Testosterone Cypionate caused unreasonable, dangerous side effects, Defendants continued to market Androgel, Axiron and Testosterone Cypionate to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that Androgel, Axiron and Testosterone Cypionate marketing materials claim are caused by "Low T".

143. At all times material hereto, Defendants misbranded the Androgel, Axiron and Testosterone Cypionate products on an on-going and continuous basis, and failed to warn physicians and patients that Androgel, Axiron and Testosterone Cypionate was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

144. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with Androgel, Axiron or Testosterone Cypionate use.

145. As marketed, detailed, and promoted to physicians, including Plaintiff's prescribing physician, Defendants failed to warn that Androgel, Axiron or Testosterone Cypionate caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

146. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

147. Defendants' negligence was a proximate cause of the John C. Hall's injuries, harm, economic loss which Plaintiff suffered as a direct and proximate result of his reasonably anticipated use of Androgel, Axiron and Testosterone Cypionate.

Count Three – Breach of Implied Warranty

148. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

149. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Androgel, Axiron and Testosterone Cypionate were of merchantable quality and safe and fit for the use for which it was intended.

150. Specifically, the Defendants warranted to Plaintiff that its products were intended to treat a condition called "LowT" and that it was safe and fit for that use, but the Defendants failed to disclose that "LowT" is not a recognized medical condition and that its testosterone products were not FDA approved to treat any such condition.

151. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including Androgel, Axiron and Testosterone Cypionate, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Androgel, Axiron and Testosterone Cypionate. As a result, the Plaintiff used Defendants' products as it was warranted to be intended.

152. Androgel, Axiron and Testosterone Cypionate were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that Androgel, Axiron and Testosterone Cypionate has dangerous propensities when used as intended and will cause severe injuries to users.

153. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Four - Breach of Express Warranty

154. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

155. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Androgel,

Axiron and Testosterone Cypionate were FDA approved to treat a condition called "LowT", and that it is safe, effective, fit and proper for its intended use. Plaintiff purchased Androgel, Axiron and Testosterone Cypionate relying upon these warranties.

156. In utilizing Androgel, Axiron and Testosterone Cypionate, Plaintiff relied on the skill; judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that there is no disease or medical condition called "LowT" that is recognized by any medical community, peer-reviewed journal, or learned treatise, and that Androgel, Axiron and Testosterone Cypionate are unsafe and unfit for their purported intended uses.

157. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Five - Fraud

158. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

159. Through a sophisticated and well-orchestrated marketing campaign, the Defendant set out to invent a fictitious disease/medical condition that it called "LowT", and then purposely deceived the Plaintiff and his physicians into believing that this was a real disease/medical condition and that Plaintiff suffered from it. Defendant did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "LowT". Those commonly occurring conditions were listed in the "Is It LowT Quiz", and included:

- Being tired after dinner

- Diminished ability to play sports
- Lack of energy
- Being sad
- Being grumpy
- Decreased libido

160. Each of these purported "symptoms" of "LowT" are normal and common conditions for men over the age of 40, and especially common in men over the age of 50.

161. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Androgel, Axiron and Testosterone Cypionate , and up to the present, knew that their products could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of its product could result in a dramatic increase in serum estradiol levels, yet the Defendants willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Androgel, Axiron and Testosterone Cypionate, which the Defendants had a duty to disclose.

162. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Androgel, Axiron and Testosterone Cypionate and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Androgel, Axiron and Testosterone Cypionate. Defendants knew of the foregoing, that Androgel, Axiron and Testosterone Cypionate are not safe, fit and effective for human consumption, that using Androgel, Axiron or Testosterone Cypionate is hazardous to health, and

that Androgel, Axiron and Testosterone Cypionate have a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

163. Defendants knowingly, falsely, deceptively, and inaccurately designated the physiologic decrease in men's testosterone levels and the age-related symptoms men experience with aging as a form of acquired hypogonadism with the intent to deceive physicians into prescribing Androgel, Axiron and Testosterone Cypionate for "off-label" indications for clinical use; and, to engage in "label expansion" of the Androgel, Axiron and Testosterone Cypionate products; and, to drive increasing consumer and patient demand for Androgel, Axiron and Testosterone Cypionate prescriptions.

164. Defendants knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of Androgel, Axiron and Testosterone Cypionate to physicians, to include statements concerning the effectiveness of treatment of the age-related signs and symptoms included on the "Interactive ADAM Questionnaire." There was no double-blind, placebo-controlled, randomized, sufficiently powered, and independent study or clinical investigation or clinical evidence to support the use of Androgel Axiron or Testosterone Cypionate, and no approval by the FDA to warrant promotion of these indications for clinical use.

165. Defendants knowingly, falsely, deceptively, and inaccurately designated and represented that the physiologic decline in men's testosterone levels and the age-related symptoms men experience with advancing age, as a form of "acquired hypogonadism" with the intent to confuse and deceive consumers and patients, and to foster the belief by consumers and patients, including John C. Hall, that they harbored a "disease" or pathologic medical condition that was appropriately treated with Androgel, Axiron or Testosterone Cypionate products.

166. Defendants concealed and suppressed the true facts concerning Androgel, Axiron and Testosterone Cypionate, and the actual disease for which they have been FDA approved to treat (Hypogonadism), with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe Androgel, Axiron or Testosterone Cypionate, and Plaintiff would not have used Androgel, Axiron or Testosterone Cypionate, if they were aware of the true facts concerning its dangers.

167. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of a mass marketing effort to encourage patients to seek treatment for "Low T," while having actual knowledge that Androgel, Axiron or Testosterone Cypionate were not indicated for the treatment of "Low T," nor were they proven to be clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

168. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that it provided to consumers and patients through its multi-platform marketing, promotional, educational, and awareness campaigns concerning the Androgel, Axiron and Testosterone Cypionate products and their indications for clinical use; and further knew that consumers and patients would make treatment choices and exercise treatment options about their use of the Androgel, Axiron and Testosterone Cypionate products in reliance upon this information.

169. Defendants deceived physicians by explicitly or implicitly claiming that the treatment of "Low T" was an FDA-approved clinical indication for use of Androgel, Axiron or Testosterone Cypionate, when in fact it was an "off-label" indication for clinical use.

170. Consumers, including John C. Hall, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for Androgel, Axiron and Testosterone Cypionate and the clinical safety and effectiveness profiles for Androgel, Axiron and Testosterone Cypionate, including information concerning the "off-label" use of Androgel, Axiron and/or Testosterone Cypionate products.

171. Plaintiff relied on the fraudulent and deceptive representations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that Androgel, Axiron and Testosterone Cypionate were FDA approved to treat a condition called "LowT", and that the Defendants' testosterone drugs were a safe and effective treatment for his "LowT".

172. John C. Hall would not have sought or continued treatment for "Low T" or administered Androgel, Axiron or Testosterone Cypionate had he been provided with adequate, true, accurate, and correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of Androgel, Axiron or Testosterone Cypionate, and the fact that "Low T" was not an FDA-approved indication for clinical use of Androgel, Axiron or Testosterone Cypionate.

173. John C. Hall would not have sought or continued treatment for "Low T," or administered Androgel, Axiron or Testosterone Cypionate, had he been provided with adequate, true, accurate, and correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of Androgel, Axiron or Testosterone Cypionate to treat "Low T."

174. During the detailing, marketing, and promotion to physicians, neither Defendants nor the co-promoters who were detailing Androgel, Axiron or Testosterone Cypionate on behalf of

Defendants warned physicians, including Plaintiff's prescribing physician, that Testosterone Cypionate caused or increased the risk of harm of cerebrovascular accident and neurologic injuries.

175. Defendants, through its national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including Plaintiff, about a "disease" Defendants denominated and characterized as "Low T."

176. These materials did reach Plaintiff, and he relied upon these materials in reaching his decision to purchase, use, and continue the use of Androgel, Axiron or Testosterone Cypionate throughout his course of testosterone therapy.

177. Plaintiff would not have administered Androgel, Axiron or Testosterone Cypionate to himself had the educational and informational materials made available to him by Defendants, and upon which he relied to his detriment, informed him about the risks of cardiovascular events and cerebrovascular accident with product use.

178. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Negligent Misrepresentation

179. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

180. From the time Androgel, Axiron or Testosterone Cypionate was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public,

including but not limited to the misrepresentation that "LowT" was an actual disease/medical condition for which medical treatment was indicated, and that Androgel, Axiron or Testosterone Cypionate was safe, fit, effective, and FDA approved for human consumption to treat "LowT". At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Androgel, Axiron or Testosterone Cypionate and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

181. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

182. The representations by the Defendants were in fact false, in that Androgel, Axiron or Testosterone Cypionate is not safe, fit and effective for human consumption, using Testosterone Cypionate is hazardous to health, and Androgel, Axiron or Testosterone Cypionate has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

183. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Androgel, Axiron or Testosterone Cypionate.

184. Plaintiff relied on the misrepresentations made by the Defendant to his detriment. Specifically, Plaintiff relied on representations that "LowT" was an actual disease that required medical treatment and use of prescription testosterone, that Androgel, Axiron or Testosterone

Cypionate was FDA approved to treat a condition called "LowT", and that the Defendant's testosterone drug was a safe and effective treatment for his "LowT".

185. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Androgel, Axiron or Testosterone Cypionate. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Androgel, Axiron or Testosterone Cypionate. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

186. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Seven - Design Defect

187. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

188. Defendant participated in the manufacture, sale and marketing of an exogenous testosterone drug that was FDA approved to treat a specific medical condition called Hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

189. The Defendant manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "LowT", which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendants

marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

190. Defendants manufactured, sold, and promoted this drug which contained a defective condition because the design was defective and unsafe in that it caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

191. This design defect made the drug unreasonably dangerous, yet the Defendants knowingly introduced the drug into the market.

192. The drug as manufactured by the Defendants remained unchanged and was in the same condition at the time of the injury hereafter alleged.

193. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, John C. Hall suffered serious injury, permanent injury, harm, damages, and economic and non-economic loss as alleged and described herein.

Punitive Damages Allegations

194. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

195. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Androgel, Axiron or Testosterone Cypionate users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Androgel, Axiron or Testosterone Cypionate. Defendants' outrageous and unconscionable

conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

196. Prior to the manufacturing, sale, and distribution of Androgel, Axiron and Testosterone Cypionate, respectively, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Androgel, Axiron and Testosterone Cypionate.

197. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Androgel, Axiron and Testosterone Cypionate and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Androgel, Axiron and Testosterone Cypionate. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Androgel, Axiron and Testosterone Cypionate knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

198. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against the Defendant, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Respectfully Submitted on this day, September 15, 2014.

s/ Matthew P. Teague
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